

### **REMARKS**

Claims 1, 4, 6, 8, 10, 12-17, 19 and 21-22 have been cancelled. Claims 2-3 have been amended. Claims 5, 7, 9, 11, 18, and 20 are withdrawn, but have been amended to be commensurate in scope with claims 2 and 3. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

#### **Rejection under 35 U.S.C. § 112, first paragraph - enablement**

Claims 2-4 and 22 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a drug combination comprising lactoferrin and (1) a TLR3 ligand (e.g. poly I:C) and wherein the drug combination is (2) effective in mice, does not reasonably provide enablement for a combination comprising lactoferrin and (1) any non-TLR3 ligand or (2) for use in animals other than mice, including humans.

This ground of rejection is addressed by amendment. Claim 2 has been amended to recite the specific exemplified TLR3 ligand, polyinosinic-polycytidylic acid, which the Examiner has indicated as enabled.

The claims have also been amended to recite “non-human animal” as suggested on page 3 of the Office Action, first full paragraph. Applicants assert that experiments in mice are indicative of success in other animal species, at least non-human animal species to which the claims are now limited. Furthermore, the specification at page 12, first full paragraph, provides guidance as to which non-human animals the claimed compositions may be administered. Applicants respectfully submit that the present claims are enabled by the specification.

In view of Applicants’ amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

#### **Rejection under 35 U.S.C. § 103(a)**

Claims 2-4 and 22 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Wang, et al. in view of Schmidt, et al. and further in view of Decicco, et al.

**Application No.:** 10/573,564  
**Filing Date:** March 27, 2006

The claims have been amended to recite the specific dosing schedule described in Example 2 of the present specification.

Wang, et al. teach administration of lactoferrin for 3 days (page 1023, col. 1, line 15). Decicco, et al. teach a single intraperitoneal injection of polyinosinic-polycytidylic acid. However, none of the cited references teach or suggest the combination of lactoferrin and polyinosinic-polycytidylic acid with the dosing schedule as now claimed.

Furthermore, as can be seen by the data in the present specification (Table 1 on page 19) the claimed composition and dosages lead to unexpectedly high levels of NK cells. Both percentage of NK cells and Number of NK cells is markedly increased when lactoferrin is provided as 7 doses at a level of “divided doses in an amount of 10 to 2000 mg/day/kg body weight” and the polyinosinic-polycytidylic acid is administered at 5 days after the administration of the lactoferrin “in an amount of 10 to 1000 µg/day/kg body weight”. None of the cited references taken alone or in combination teach or suggest such a marked increase in NK cells. The increase in NK cells with the claimed composition and dosage was unexpected and could not have been predicted based upon the cited references.

In view of Applicants’ amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

### **Rejoinder**

Withdrawn method claims 5, 7, 9, 11, 18, and 20 have been amended to be commensurate in scope with composition claims 2 and 3 which are believed to be in condition for allowance. Rejoinder of the withdrawn method claims is respectfully requested.

### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present

**Application No.:** 10/573,564  
**Filing Date:** March 27, 2006

disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

**Co-Pending Applications of Assignee**

Applicant wishes to draw to the Examiner's attention to the following co-pending applications of the present application's assignee. Item in **Bold** is the present application.

| Serial Number | Title  | Filed    |
|---------------|--|----------|
| 10/110,972    | METHOD OF DETECTING AND IDENTIFYING THICKNESS OF SHEET-LIKE FOOD, METHOD OF MANUFACTURING SHEET-LIKE FOOD, AND DEVICES THEREFOR                                    | 04/18/02 |
| 10/432,551    | INTERFERON THERAPEUTIC EFFECT-POTENTIATING AGENTS  | 05/23/03 |
| 10/451,587    | INTERLEUKIN-18 INDUCING AGENT  | 06/23/03 |
| 10/492,306    | METHOD OF PRESERVING FOOD, AND METHOD OF PRODUCING NON-FROZEN WATER  | 04/12/04 |
| 10/709,674    | BIFIDOBACTERIUM LONGUM   | 05/21/04 |
| 10/510,088    | CYSTEINE PROTEASE INHIBITOR  | 10/04/04 |
| 10/513,523    | PROTEASE INHIBITOR   | 11/04/04 |
| 10/518,018    | INTERLEUKIN-6 SUPPRESSIVE AGENT  | 12/15/04 |
| 10/526,988    | CONTINUOUS EMULSIFICATION PROCESS FOR PROCESS CHEESE TYPE AND EQUIPMENT THEREFORE, AND CONTINUOUS PRODUCTION METHOD FOR PROCESS CHEESE TYPE AND EQUIPMENT THEREFOR | 03/07/05 |
| 10/543,491    | METHOD OF DETECTING BIFIDOBACTERIUM INFANTIS   | 07/26/05 |
| 10/548,927    | PROCESS FOR PRODUCING CHEESE   | 09/12/05 |
| 10/562,384    | CONTAINER, FROZEN MATERIAL PACKAGING BODY, AND METHOD OF MANUFACTURING PACKAGING BODY  | 12/27/05 |
| 10/564,302    | DRUG FOR CANCER THERAPY  | 01/10/06 |
| 10/564,464    | GLYCOSIDE HAVING 4-METHYLERGOST-7-EN-OL SKELETON AND HYPERGLYCEMIA IMPROVING AGENT   | 01/12/06 |

**Application No.:** 10/573,564  
**Filing Date:** March 27, 2006

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|-------------------|---|-----------------|
| 10/566,541        | CHEWABLE CAPSULE AND PRODUCTION METHOD THEREOF  | 01/27/06        |
| 10/572,099        | DRUG AND FOOD OR DRINK FOR IMPROVING HYPERGLYCEMIA  | 03/16/06        |
| 10/572,404        | DRUG AND FOOD OR DRINK FOR IMPROVING HYPERGLYCEMIA  | 03/16/06        |
| <b>10/573,564</b> | <b>DRUG AND METHOD FOR PROLIFERATING NATURAL KILLER CELLS</b>                               | <b>03/27/06</b> |
| 11/580,173        | INTERLEUKIN-18 INDUCER  | 10/12/06        |
| 11/576,652        | DRUG AND FOOD OR DRINK FOR IMPROVING PANCREATIC FUNCTIONS                                   | 04/04/07        |
| 11/576,676        | DRUG AND FOOD OR DRINK FOR IMPROVING PANCREATIC FUNCTIONS                                   | 04/04/07        |
| 11/577,301        | DRUG AND FOOD OR DRINK FOR IMPROVING PANCREATIC FUNCTIONS                                   | 04/13/07        |
| 11/815,428        | ALOE VERA EXTRACT, METHOD OF PRODUCING ALOE VERA EXTRACT, AND HYPERGLYCEMIA IMPROVING AGENT | 08/02/07        |
| 11/913022         | AGENT FOR INHIBITING VISCERAL FAT ACCUMULATION  | 29-Oct-2007     |
| 11/913758         | AGENT FOR INHIBITING VISCERAL FAT ACCUMULATION  | 06-Nov-2007     |
| 11/916008         | AGENT FOR IMPROVING INSULIN RESISTANCE  | 29-Nov-2007     |
| 11/917870         | AGENT FOR IMPROVING INSULIN RESISTANCE  | 17-Dec-2007     |
| 11/994823         | METHOD FOR DETECTION OF MICROORGANISM AND KIT FOR DETECTION OF MICROORGANISM                | 04-Jan-2008     |
| 11/996422         | METHOD FOR DETECTION OF MICROORGANISM AND KIT FOR DETECTION OF MICROORGANISM                | 22-Jan-2008     |

### **CONCLUSION**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

**Application No.:** 10/573,564  
**Filing Date:** March 27, 2006

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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